

REMARKS

This Amendment and Response is filed in response to the Office Action mailed July 3, 2007 with regard to the above-referenced Patent Application. Claims 1-20 were pending. By this Amendment and Response, claims 1-20 have been amended and claims 21-52 have been added. Applicants express appreciation for the Interview conducted with the undersigned attorney on May 3, 2007.

U.S. Patent No. 6,736,825 and the Rejection under 35 U.S.C. § 101

In the Office Action dated August 11, 2006, the claims were rejected as not being patentable under 35 U.S.C. § 101 as the same invention was claimed in claims 1-20 as originally filed in the Present Application and in claims 1-20 of U.S. Patent No. 6,736,825, the parent of the Present Application. To overcome this rejection, the claims were amended in the Amendment and Response filed on February 12, 2007. Independent claims 1 and 18 were amended to recite that "the first ring means and second ring means are configured to hold the first vessel and second vessel together without requiring penetration of at least one of the vessels." Independent claims 7, 19 and 20 were similarly amended to recite that "the first ring and second ring are configured to hold the first vessel and second vessel together without requiring penetration of at least one of the vessels."

U.S. Patent No. 6,736,825 and Huxel et al. and

In the Response filed on February 12, 2007, Applicants asserted that the amended claims were also patentable over U.S. Patent No. 6,503,259 issued to Huxel et al. (hereinafter "Huxel et al."). However, it should be understood that Applicants strongly disagree with the characterization of Huxel et al. with respect to the claims as originally filed in the Present Application which were identical to those which issued in U.S. Patent No. 6,736,825.

Huxel et al. does not disclose rings rather the device disclosed in Huxel et al. comprises a plurality of components that are positioned in a circular arrangement and remain discrete before and after they are attached together as indicated in columns 3-4 of Huxel et al. Each of the fasteners 11 comprise a tissue piercing element 12 and a receiver element 14. As stated at column 3, lines 59-60, "each of the fasteners 11 is structurally independent." As described at column 3, lines 36-47, the plurality of fasteners "approximate concentric segmented rings." It is further stated, at column 3, line 66 to column 4, line 7, that:

"[e]ach interlocked pair 12, 14 is structurally independent from any other pair of interlocked pair of interlocked elements 12, 14, allowing the interlocked pairs of elements 12, 14 to move independently of the others, being constrained and held in relative proximity by their affixation to a common substrate, e.g., peripheral flanges of tissue on the conjoined severed ends of the intestine. This relative structural independent gives rise to what can be described as 'flexibility' of the fastener array 10."

During the prosecution of U.S. Patent 6,736,825, Huxel et al. was cited and considered. The claims were not rejected based on Huxel et al., however, as it is clear that Huxel et

al. does not disclose the subject matter of the claims. Rather, Huxel et al. disclose structures that are positioned in a circle and have structural independence that allows for movement after attachment to the tissue. Accordingly, it was understood during the prosecution of U.S. Patent 6,736,825 that the term “ring” was limited, as construed in light of the specification, to an integral structure and/or a plurality of connected components and was patentable for at least those reasons with respect to Huxel et al. As described below, other reasons also support patentability of the claims in U.S. Patent 6,736,825.

Claim 7 of U.S. Patent 6,736,825 recites that “each ring is adapted to expand and contract” and a similar limitation is recited in claim 1 in “means-plus-function” format. In contrast, the tissue is relied on in Huxel et al. for expansion and contraction of the entire device while the structurally independent fasteners 11 merely move with the tissue. For this additional reason, claims 1 and 7 are patentable over Huxel et al. and the other cited prior art references.

Claim 19 recites that

“each ring is adapted to be in a compressed position as the first vessel and second vessel are anastomosed together such that each respective ring opening and respective vessel opening have an initial diameter, and

wherein at least one ring is adapted to radially expand to a deployed position after the first vessel and second vessel are anastomosed together such that each ring and vessel opening has a greater diameter than the initial diameter of each respective ring and vessel opening.”

Claim 18 recites the same functionality but in means-plus-function format. Because the rings are essentially springs, the rings can be compressed into a

compressed position and then expand into a deployed or resting position. Of course, the rings can further expand to an expanded position and then return to the deployed or resting position. In contrast, the device in Huxel et al. only moves as the blood vessel moves so the tissue piercing elements 12 and the receiver elements 14 move between an initial state, and an expanded state then back to the initial state. For this additional reason, claims 18 and 19 of U.S. Patent No. 6,736,825 are patentable over Huxel et al. and the other cited prior art references.

Claim 20 recites that each ring has a plurality of flexible segments that enable each ring opening and vessel opening to change in diameter as each ring expands and contracts in response to changes in fluid pressure. As discussed above, Huxel et al. does not disclose rings merely a collection of independent components arranged in a circle. None of these components are flexible. For this additional reason, claim 20 of U.S. Patent No. 6,736,825 is patentable over Huxel et al. and the other cited prior art references.

Rejection under 35 U.S.C. § 103(a) in the Office Action Dated July 3, 2007

Claims 1-20 of the Present Application were rejected under 35 U.S.C. § 103(a) in the Office Action dated July 3, 2007 based on Huxel et al. and U.S. Patent No. 4,467,804 issued to Hardy et al. Claims 1-20 of the Present Application respectively recite all of the limitations recited in claims 1-20 of U.S. Patent No. 6,736,825. So claims 1-20 of the Present Application are patentable for at least the same reasons as set forth above with respect to U.S. Patent No. 6,736,825.

Claims 7, 19 and 20 recite that “the first ring and the second ring are configured to hold the first vessel and second vessel together without requiring penetration of at least one of the vessels.” Claims 1 and 18 recite the same functionality but in means-plus-function format. As provided in the previous Response, the anastomotic device disclosed in Huxel et al. requires that the tissue of both vessels is penetrated by “pins 20” while the embodiments disclosed in the Present Application require that only one of the vessels is purposefully penetrated in order to hold the vessels together or do not require that either of the vessels are penetrated in order to be held together.

The device disclosed in Hardy et al. is a rigid ring which cannot move radially and eventually disintegrates. As stated in Hardy et al. at column 1, lines 14-15, the disclosed device has use for attaching the severed ends of the intestine after surgery. At column 1, lines 55-63 of Hardy et al. it is indicated that a connector which disintegrates in a relatively short period of time is preferred as “a permanent connector will tend to prevent the changes in diameter which are necessary for proper functioning of the intestine.” The intestines do not expand and contract in the dynamic manner of an artery so the ability to move as recited in the claims 1, 7, 18-20 was not needed by the device in Hardy et al. The difficulty of maintaining tissue on a ring that moves in the manner recited in claims 1, 7, 18-20 is substantially more challenging than it is for a ring with a fixed configured like that disclosed in Hardy et al. Since Hardy et al. viewed disintegration as the solution for not interfering with vessel movement and vessel attachment is significantly more difficult on a ring that moves as recited, one of ordinary

skill in the art would not have found Hardy et al., in combination with Huxel et al., instructive with respect to the recited inventions. Also, as previously indicated, Huxel et al. achieves "flexibility" via a plurality of discrete, structurally independent components. So the combination of Huxel et al. and Hardy et al. does not make the recited inventions obvious.

Claims 31 and 42 are independent method claims. As discussed above, the rings recited in the claims of the Present Application and its parent, U.S. Patent No. 6,736,825, are obviated by the discrete components disclosed in Huxel et al. so for at least this reason, claims 31 and 42 are patentable over the cited prior art. Claims 31 and 42 also recites that each ring is capable of expanding and contracting before the rings are locked together. The discrete components disclosed in Huxel et al. are not capable of achieving this function. Claim 42 further recites that the method involves anastomosis of an end of a first vessel to a side of a second vessel.

Each of these claims is fully supported by the application as originally filed. In addition, it is believed that each of the now-pending claims is patentable in its present form, and favorable consideration and allowance thereof is respectfully requested. As mentioned above, if the Examiner finds any remaining impediment to the prompt allowance of this application, please contact the undersigned attorney.

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Respectfully submitted,

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